K071622

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4 510(k) Summary of Safety and Effectiveness

Manufacturer/Sponsor	Arthrex, Inc.1370 Creekside Boulevard Naples, Florida 34108-1945
510(k) Contact	Ann Waterhouse, RAC Regulatory Affairs Project Manager Telephone: 239/643.5553, ext. 1179 Fax: 239/598.5508 Email: awaterhouse@arthrex.com
Trade Name	Arthrex FiberWire®
Common Name	Suture, non-absorbable
Product Code - Classification Name	GAT, Suture, Non-absorbable, Synthetic, Polyethylene: 21 CFR 878.5000 GAP, Suture Non-absorbable, Silk: 21 CFR 878.5030
Predicate Device	K041589, FiberWire® K041553, FiberWire® Suture Grafting Kit
Device Description and Intended Use	Arthrex FiberWire® configurations consist of single strand suture with or without needles, suture with stiffened ends, suture chains, and FiberTape®. The Arthrex FiberWire® suture configurations are intended for use in soft tissue approximation and or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.
Substantial Equivalence Summary	The Arthrex FiberWire® is substantially equivalent to the predicate Arthrex FiberWire® in which the basic features and intended uses are the same. Any differences between the FiberWire and the predicate K041589/K041553 are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the new FiberWire® is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Arthrex, Inc.
% Ms. Ann Waterhouse, RAC
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K071622
Trade/Device Name: Arthrex FiberWire®
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: GAT
Dated: June 13, 2007
Received: June 19, 2007

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indications for Use Form

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Indications for Use

510(k) Number: K071622

Device Name: Arthrex FiberWire®

The Arthrex FiberWire® suture configurations are intended for use in soft tissue approximation and or ligation. These sutures may be incorporated, as components, into surgeries where constructs including those with allograft or autograft tissues are used for repair.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071622